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(71) Applicant (*for all designated States except US*): HEARTEN MEDICAL, INC. [US/US]; Suite A, 15042 Parkway Loop, Tustin, CA 92780 (US).

(72) Inventor; and
(75) Inventor/Applicant (*for US only*): LAUFER, Michael, D. [US/US]; 1259 El Camino Real #211, Menlo Park, CA 94025 (US).

(74) Agents: KREBS, Robert, E. et al.; Burns, Doane, Swecker & Mathis, L.L.P., P.O. Box 1404, Alexandria, VA 22313-1404 (US).

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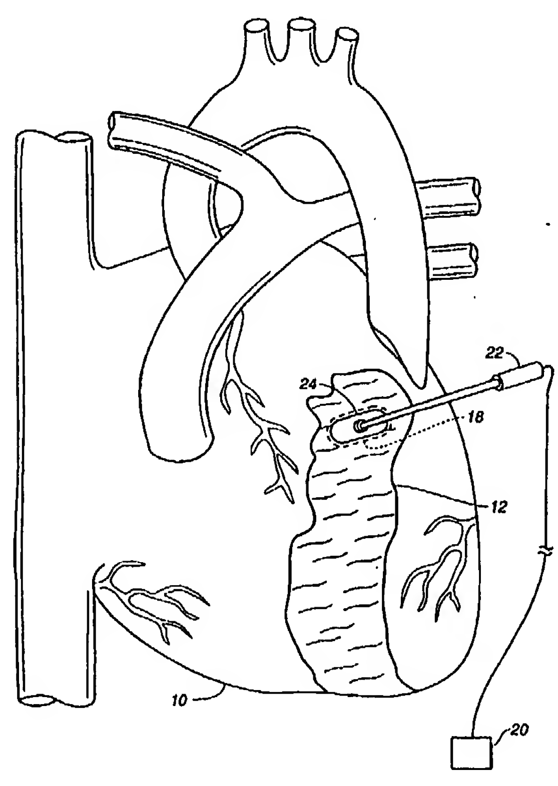
(54) Title: DEVICE FOR THE TREATMENT OF INFARCTED TISSUE AND METHOD OF USING THE DEVICE

(57) Abstract

This invention is a device and method for treating myocardial infarction by selectively heating the infarct scar to reduce the size of the scar tissue area (18) by shrinking the tissue in the heart (10), stiffen the floppy portion of the scar tissue, reduce the ventricular systolic wall tension, and increase the overall pumping efficiency of the infarcted heart (10) by eliminating a ventricular aneurysm, if present. The heat can be applied to, or induced in, the infarct scar. Force can also be applied to assist the reduction of the size of the scar (18) using the device of the present invention which has a heating element (24), and a scissor-like clamp (26) for squeezing two portions of the infarct scar together.



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DEVICE FOR THE TREATMENT OF INFARCTED TISSUE AND METHOD OF USING THE DEVICE

FIELD OF THE INVENTION

The present invention is related generally to the modification of heart tissue for the treatment of myocardial infarction.

BACKGROUND OF THE INVENTION

As is well known, the heart has four chambers for receiving and pumping blood to various parts of the body. During normal operation of the heart, oxygen-poor blood returning from the body enters the right atrium. The right atrium fills with blood and eventually contracts to expel the blood through the tricuspid valve to the right ventricle. Contraction of the right ventricle ejects the blood in a pulse-like manner into the pulmonary artery and each lung. The oxygenated blood leaves the lungs through the pulmonary veins and fills the left atrium. The left atrium fills with blood and eventually contracts to expel the blood through the mitral valve to the left ventricle. Contraction of the left ventricle forces blood through the aorta to eventually deliver the oxygenated blood to the rest of the body.

Myocardial infarction (i.e., heart attack) can result in congestive heart failure. Congestive heart failure is a condition wherein the heart can not pump enough blood. When patients have a heart attack, part of the circulation to the heart wall muscle is lost usually do to a blood clot which dislodges from a larger artery and obstructs a coronary artery. If the clot is not dissolved within about 3 to 4 hours, the muscle which lost its blood supply necroses and subsequently becomes a scar. The scarred muscle is not contractile, therefore it does not contribute, to the pumping ability of the heart. In addition, the scarred muscle is elastic (i.e., floppy) which further reduces the efficiency of the heart because a portion of the force created by the remaining healthy muscle bulges out the scarred tissue (i.e., ventricular aneurysm) instead of pumping the blood out of the heart.

Congestive heart failure is generally treated with lots of rest, a low-salt diet, and medications such as A.C.E. inhibitors, digitalis, vasodilators and diuretics. In some myocardial infarction instances, the scarred muscle is cut out of the heart and the remaining portions of the heart are sutured (i.e., aneurysmectomy). In limited circumstances a heart transplant may be performed.

Collagen-containing tissue is ubiquitous in the human body and makes up a substantial portion of the scar. Collagen demonstrates several unique characteristics not found in other tissues. Intermolecular cross links provide collagen-containing tissue with unique physical properties of high tensile strength and substantial elasticity. A property of collagen is shrinkage of collagen fibers when elevated in temperature. This molecular response to temperature elevation is believed to be the result of rupture of the collagen stabilizing cross links and immediate contraction of the collagen fibers to about one-third of their original linear dimension or the result of a change in the hydration of the tissue. Another property of collagen is that the caliber of the individual fibers increases greatly, over four fold, without changing the structural integrity of the connective tissue.

There has been discussion in the existing literature regarding alteration of collagen-containing tissue in different parts of the body. One known technique for effective use of this knowledge of the properties of collagen is through the use of infrared laser energy to effect tissue heating. The use of infrared laser energy as a corneal collagen shrinking tool of the eye has been described and relates to laser keratoplasty, as set forth in U.S. Patent No. 4,976,709. The importance of controlling the localization, timing and intensity of laser energy delivery is recognized as paramount in providing the desired soft tissue shrinkage effects without creating excessive damage to the surrounding non-target tissues. Another known technique of altering collagen is described in U.S. Patent No. 5,458,596 to treat joints. U.S. Patent No. 5,437,664 describes using a catheter for venous occlusion and coagulation of blood.

Thermal destruction (i.e., ablation) of problematic myocardial tissue (i.e., arrhythmogenic focus) is a therapeutic procedure used with increasing frequency for the treatment of cardiac arrhythmias (e.g., ventricular tachycardia) as described in

U.S. Patent No. 5,246,438. The treatment of cardiac arrhythmias involves treating electrically problematic but otherwise healthy tissue. As a result one goal of ablation is to localize the heat as much as possible so as to restrict the ablation to only the problematic healthy tissue.

SUMMARY OF THE INVENTION

The present invention provides a device and method for treating infarct scar tissue of a mammalian heart by selectively heating the infarct scar to reduce the size of the scar tissue surface area, increase the cross-section of the scar tissue, stiffen the floppy portion of the scar tissue, reduce the ventricular systolic wall tension, and increase the overall pumping efficiency of the infarcted heart by eliminating the ventricular aneurysm, if present. The present invention preferably does not affect the healthy heart tissue or ablate the infarcted tissue. Furthermore, preferably the present invention diffuses the heat over the infarcted area.

The method is similar to an annealing process wherein the scar tissue undergoes heating and then is allowed to cool slowly. The heat can be applied to or induced in the infarct scar. Force can also be applied in accordance with the present invention to assist the reduction of the size of the scar. Generally speaking, besides reducing the surface area of the scarred tissue, the present invention alters the material properties of the infarct scar such as making it stiffer and less elastic.

In one aspect of the invention, there is provided an apparatus for heating an infarct scar in a heart having a heating element having a projection for piercing the scar and a mechanism for squeezing at least two portions of the scar toward each other.

In another aspect of the invention, there is provided a method for treating an infarct scar in a heart including the step of energizing a heating element to raise the temperature of the infarct scar to a temperature sufficient to reduce the surface area of the infarct scar.

In yet another aspect of the invention, there is provided a method for training a person to perform a method for treating an infarct scar in a heart including the steps of demonstrating or instructing how to do the following step of energizing a heating

element to raise the temperature of the infarct scar to a temperature sufficient to reduce the surface area of the infarct scar.

In still another aspect of the invention, there is provided a modified mammalian heart having a contracted infarct scar tissue portion diminished in its surface area and stiffened.

In yet another aspect of the invention, there is provided a method for treating an infarct scar in a heart including the step of energizing a heating element to raise the temperature of the infarct scar to a temperature sufficient to reduce the ventricular systolic wall tension.

BRIEF DESCRIPTION OF THE DRAWINGS

As used herein, like reference numerals will designate similar elements in the various embodiments of the present invention wherein:

FIG. 1 is a mammalian heart with electrodes inserted in an infarcted area;

FIG. 2 is a mammalian heart with a radio-frequency heating element in contact with the infarcted area;

FIG. 3 is a front view of a device for heating and squeezing portions of the infarcted area together;

FIG. 4 is a side view of the device of FIG. 3; and

FIG. 5 is a top view of the device of FIG. 2 during treatment of the infarcted area.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides a device and method for altering the material properties of collagen-containing infarcted tissue in a patient's heart. There also is provided a method of training a person to perform a method for treating an infarct scar in a mammalian heart. The invention is used to accurately control the inducement of heat or application of heat within a specific thermal range, and deliver thermal energy to the collagen-containing infarcted tissue to reduce the size of the scar tissue area by shrinking the infarcted tissue in the heart and stiffening the floppy portion of the scar tissue without ablating the tissue. As a result, the overall pumping

efficiency of the infarcted heart is increased. Likewise, a modified mammalian heart having a contracted infarct scar tissue portion diminished in its surface area and reduced ventricular systolic wall tension results.

Referring initially to FIG. 1, there is illustrated a heart 10 having an infarcted region or portion 12. The infarcted portion 12 of the heart can be accessed with conventional open chest surgery or with arthroscopic techniques. A positive electrode 14 and negative electrode 16 are inserted in a portion of the infarcted portion 12 to induce resistive heating in the infarct scar in the desired treatment area 18 when energy is applied across the electrodes. Alternatively, the positive and negative electrodes can be placed in contact with the infarcted scar. The positive and negative electrodes function as a heating element as they are energized to raise the temperature of the scar in the desired treatment area 18 to a temperature sufficient to reduce the surface area of the scar without ablating the scar tissue or damaging the healthy tissue surrounding the infarcted portion 12. The term "heating element" as used herein encompasses elements that apply energy thereby inducing heat in the tissue as well as to elements that apply heat to the tissue. In a preferred embodiment, the scar is heated to a temperature in the range of about 40 degrees Celsius to about 75 degrees Celsius, more preferably about 60 degrees Celsius to about 65 degrees Celsius. After the desired treatment area 18 has been heated, it is allowed to cool. Energy is no longer applied after there has been sufficient shrinkage of the scar tissue. Sufficient shrinkage may be detected visually, mechanically, echocardiograhically, ventriculographically with x-ray, fluoroscopically or with appropriate feed back variables, such as impedance monitoring, temperature monitoring, or any other suitable method. The electrodes or heating element can then be moved to another portion of the infarcted portion 12 for treatment. It is believed, without being limited to a particular theory, that as the infarct scar is heated the collagen fibers straighten then as the collagen fibers cool they re-entwine or refold around each other becoming shorter, tighter, thicker, stronger, stiffer, or some combination of these qualities.

The method is contemplated to be used with any suitable appliance for applying radiant energy, thermal energy, or to otherwise heat the infarcted tissue and reduce the area of the infarcted tissue. For example, a radio-frequency generator 20

and heating element applicator 22 can be used (FIG. 2). When the heating element 24 of the applicator 22 is positioned at the desired treatment site, the radio-frequency generator 20 is activated to provide suitable energy, preferably at a selected frequency in the range of 10 megahertz to 1000 megahertz, to heat the scar tissue to a temperature sufficient to reduce the surface area of the scar without ablating the scar tissue or damaging the healthy tissue surrounding the infarcted area 12. Preferably, the emitted energy is converted within the scar tissue into heat in the range of about 40 degrees Celsius to about 75 degrees Celsius, more preferably in the range of about 60 degrees Celsius to about 65 degrees Celsius. The radio-frequency energy is preferably applied at low power levels (e.g., 1 to 20 watts). Suitable radio-frequency power sources are readily commercially available. In one embodiment, the radio-frequency generator 20 has a single channel, delivering approximately 1 to 20 watts of energy and possessing continuous delivery capability.

The heating element 24 of the applicator 22, as shown in FIG. 2, operates as a unipolar electrode. An outer electrode (not shown) having a much larger surface area than the heating element 24 is placed on the outer surface of the patient's body. For example, an external metal mesh or solid plate is placed on the skin. Both electrodes are connected to radio-frequency generator 20 which produces an electric field at a high frequency within the patient's body. Because the surface area of the heating element 24 is much smaller than that of the outer electrode, the density of the high frequency electric field is much higher around the heating element. The electric field reaches its highest density between the two electrodes in the region near the heating element 24. The increased density of the field around the heating element 24 produces localized heating of the scar tissue in the treatment area 18. Alternatively, two electrodes can be placed on the scar and energized in a bipolar fashion.

Referring to FIGS. 3-5, another embodiment for a heating device is shown. The heating device of FIGS. 3-5 is comprised of a scissor-like clamp 26 having crossing arms 28 and 30 which are connected by pin 32 near the mid-point of the arms. At the proximal end of arms 28 and 30 are handles 34 and 36, respectively, and at their distal ends 38 and 40, respectively, a plurality of protrusions 42 spaced along elongated members 44 and 46, respectively. An optional releasable lock 48 is

located between arms 28 and 30. Likewise, an optional fixed force spring can be located between the arms. Attached to arm 28 is a positive electrode 50 and attached to arm 30 is negative electrode 52. Each of the arms 28 and 30 are free to rotate about pin 32 and are electrically isolated from each other such that when a potential is applied between the electrodes 50 and 52 there is no short between the arms.

The clamp 26 is used by a surgeon (or an individual demonstrating) to squeeze and shrink a portion of the area of the infarct scar tissue 12. (Likewise, an individual can instruct a surgeon on how to accomplish the method of the present invention with the clamp 26 or other embodiments disclosed herein.) The surgeon grabs (or pierces the scar tissue with the protrusions 42, if present) and squeezes the two portions of the scar tissue toward each other by actuating the clamp with the handles 34 and 36 (FIG. 5). The protrusions 42 when present are conductive elements. The positive and negative electrodes are then energized by the surgeon to function as a heating element to raise the temperature of the scar in the desired treatment area 18 to a temperature sufficient to reduce the surface area of the scar without ablating the scar tissue or damaging the healthy tissue surrounding the infarcted portion 12. The protrusions can be used to treat endocardial, sub-endocardial and transmural infarcted areas. The protrusions can have insulated proximal portions such that the distal portions are used to treat endocardial infarcted areas. Alternatively, the protrusions can have insulated distal portions such that the proximal portions are used to treat sub-endocardial infarcted areas. The protrusions can be uninsulated to treat transmural infarcted areas. Likewise, only a portion of a side of a protrusion may be insulated.

The clamp 26 is beneficial in applying force to the infarcted tissue to assist in the shrinking process. The releasable lock 48 or fixed force spring can be used to preset the distance which the two portions of the scar are going to be moved toward each other. Alternatively, the releasable lock can be used to hold the two portions steady at a given distance during the heating process. The elongated members 44 and 46 are generally not brought close together so that a larger area of the scar can be treated. Generally, the elongated members 44 and 46 are actuated toward each other so as to apply a relatively small amount of force to assist the shrinking process. The clamp 26 illustrated in FIGS. 3-5 utilizes resistive heating of the scar tissue, but it is

also within the scope of the invention that a radio-frequency generator and electrodes, as well as other means to be described below, can be utilized.

The heating element of any of the embodiments can be made to provide protection against overheating of the scar tissue. Techniques, for example temperature monitoring or electrical characteristic monitoring (e.g., impedance), can be utilized in a system which shuts down the application of energy to the heating element to avoid ablating the tissue or damaging healthy tissue. The surgeon can, if desired, override the feedback control system. A microprocessor can be included and incorporated into the feedback control system to switch the power on and off, as well as modulate the power. The microprocessor can serve as a controller to watch the temperature and modulate the power in order to avoid over-heating of the tissue. The heating element can be synchronized with the ECG so that the heart wall is in diastole. Furthermore, the system can include auditory or visual feedback indicators for signalling when shrinkage, temperature, or other variables are occurring and also when any have reached or exceeded desired conditions.

It is to be understood that other forms of energy, in addition to those discussed above, such as microwaves, ultrasound, and light (either coherent or incoherent sources) can be used, and that the thermal energy generated from a hot fluid element (e.g., liquids, gases, combinations of liquids and gases, etc.), a curie point element, or similar elements can be used as well. Heating element 42 in accordance with any of the embodiments can be a number of different materials including but not limited to conductive polymer, stainless steel, platinum, or other noble metals.

While several particular embodiments of the invention have been illustrated and described, it will be apparent that various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

Claims:

1. An apparatus for heating an infarct scar in a heart, comprising:
a heating element; and
means for contacting and squeezing at least two portions of a same surface of the scar toward each other.

2. The apparatus of Claim 1 wherein the heating element comprises electrodes for heating the scar.

3. The apparatus of Claim 1 further comprising a radio frequency generator for energizing the heating element.

4. The apparatus of Claim 1 further comprising a projection for piercing the scar.

5. The apparatus of Claim 4 wherein the projection comprises a plurality of conductive elements.

6. The apparatus of Claim 4 wherein a portion of the projection is insulated.

7. The apparatus of Claim 1 wherein the means for contacting and squeezing comprises a scissor-like clamp.

8. The apparatus of Claim 7 wherein the scissor-like clamp further comprises a releasable lock.

9. The apparatus of Claim 7 wherein the scissor-like clamp further comprises a fixed force spring.

10. The apparatus of Claim 1 wherein the heating element comprises microwave means for heating the infarct scar.

11. The apparatus of Claim 1 wherein the heating element comprises ultrasound means for heating the infarct scar.

12. The apparatus of Claim 1 wherein the heating element comprises light means for heating the infarct scar.

13. The apparatus of Claim 1 wherein the heating element comprises a hot fluid element.

14. The apparatus of Claim 1 wherein the heating element comprises a unipolar electrode.

15. The apparatus of Claim 1 further comprising means for synchronizing the heating element with the ECG.

16. The apparatus of Claim 1 further comprising a feedback indicator.

17. The apparatus of Claim 16 wherein the feedback indicator is an auditory signal.

18. The apparatus of Claim 16 wherein the feedback indicator is a visual signal.

19. The apparatus of Claim 16 wherein the feedback indicator is indicative of shrinkage.

20. The apparatus of Claim 16 wherein the feedback indicator is indicative of temperature.

21. The apparatus of Claim 16 wherein the feedback indicator is indicative of electrical characteristics.

22. A method for treating an infarct scar in a heart, comprising the step of:
energizing a heating element to raise the temperature of the infarct scar to a temperature sufficient to reduce the surface area of the infarct scar.

23. The method of Claim 22 further comprising the step of:
squeezing at least two portions of the infarct scar toward each other.

24. The method of Claim 22 further comprising the steps of:
piercing the scar; and
squeezing at least two portions of the scar toward each other.

25. The method of Claim 22 further comprising the steps of:
providing an apparatus having a heating element having a projection for piercing the scar and means for squeezing at least two portions of the scar toward each other;
piercing the scar; and
squeezing at least two portions of the scar toward each other.

26. The method of Claim 22 wherein the heating element is energized by applying radio frequency energy.

27. The method of Claim 22 wherein the heating element is energized by resistive heating.

28. The method of Claim 22 wherein the scar is energized to a temperature in the range of about 40 degrees Celsius to about 75 degrees Celsius.

29. A method for training a person to perform a method for treating an infarct scar in a heart, comprising the step of:

demonstrating or instructing the performance of the following step of:

energizing a heating element to raise the temperature of the infarct scar to a temperature sufficient to reduce the surface area of the infarct scar.

30. The method of Claim 29 further comprising the step of:

squeezing at least two portions of the infarct scar toward each other.

31. The method of Claim 29 further comprising demonstrating or instructing the performance of the following steps of:

piercing the scar; and

squeezing at least two portions of the scar toward each other.

32. The method of Claim 29 further comprising the steps of:

providing an apparatus having a heating element having a projection for piercing the scar and means for squeezing at least two portions of the scar toward each other; and

demonstrating or instructing the performance of the following steps of:

piercing the scar; and

squeezing at least two portions of the scar toward each other.

33. The method of Claim 29 wherein the heating element is energized by applying radio frequency energy.

34. The method of Claim 29 wherein the heating element is energized by resistive heating.

35. The method of Claim 29 wherein the scar is energized to a temperature in the range of about 40 degrees Celsius to about 75 degrees Celsius.

36. A modified mammalian heart having a contracted infarct scar tissue portion diminished in its surface area.

37. A method for treating an infarct scar in a heart, comprising the step of:

energizing a heating element to raise the temperature of the infarct scar to a temperature sufficient to reduce the ventricular systolic wall tension.

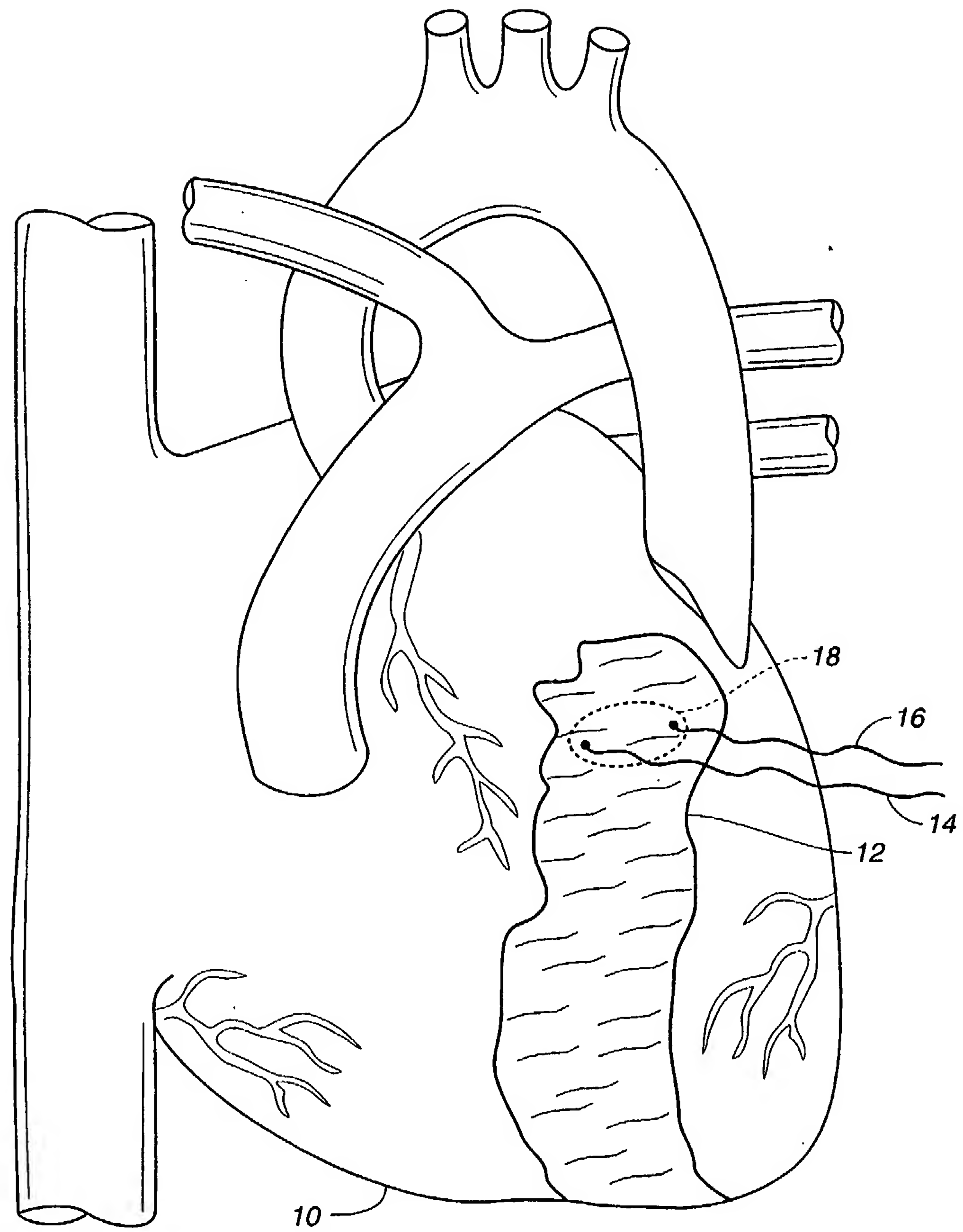

FIG._1

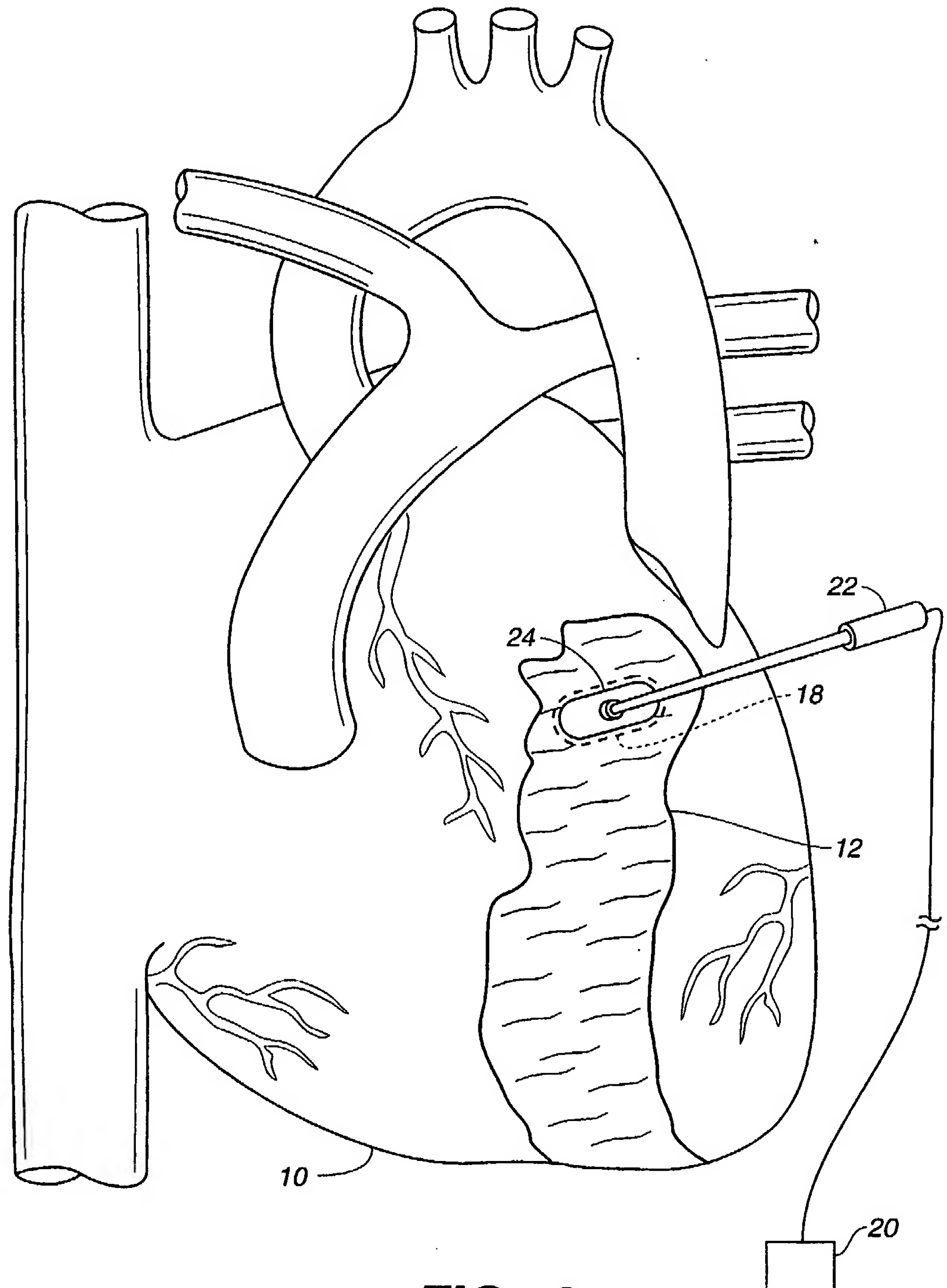

FIG._2

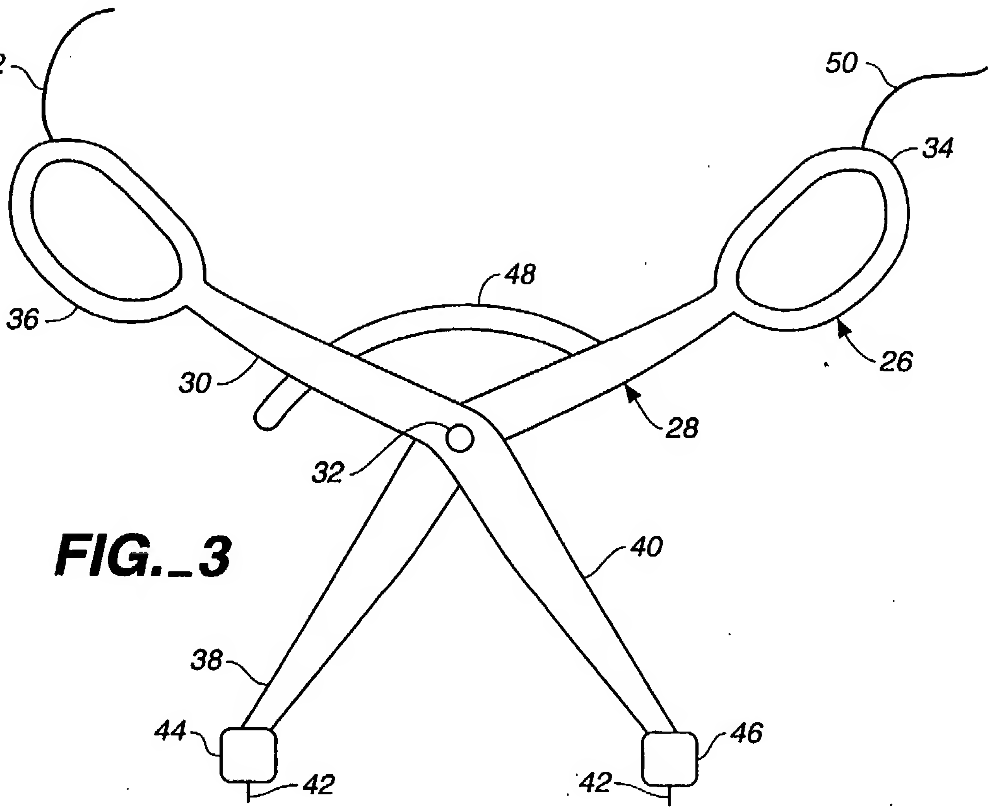
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FIG._3

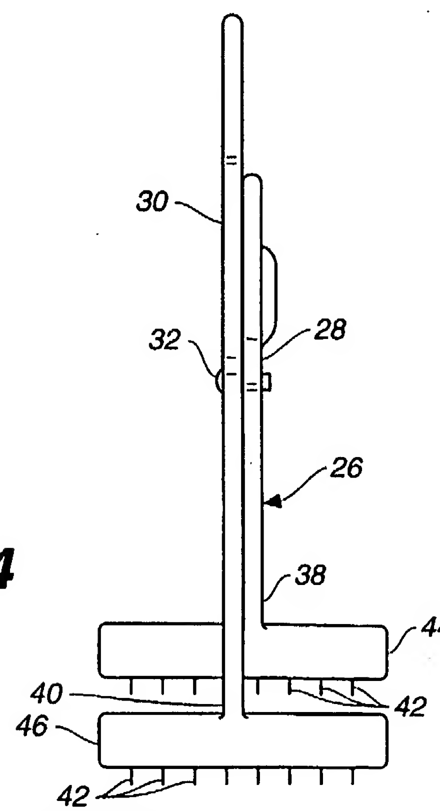
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FIG._4

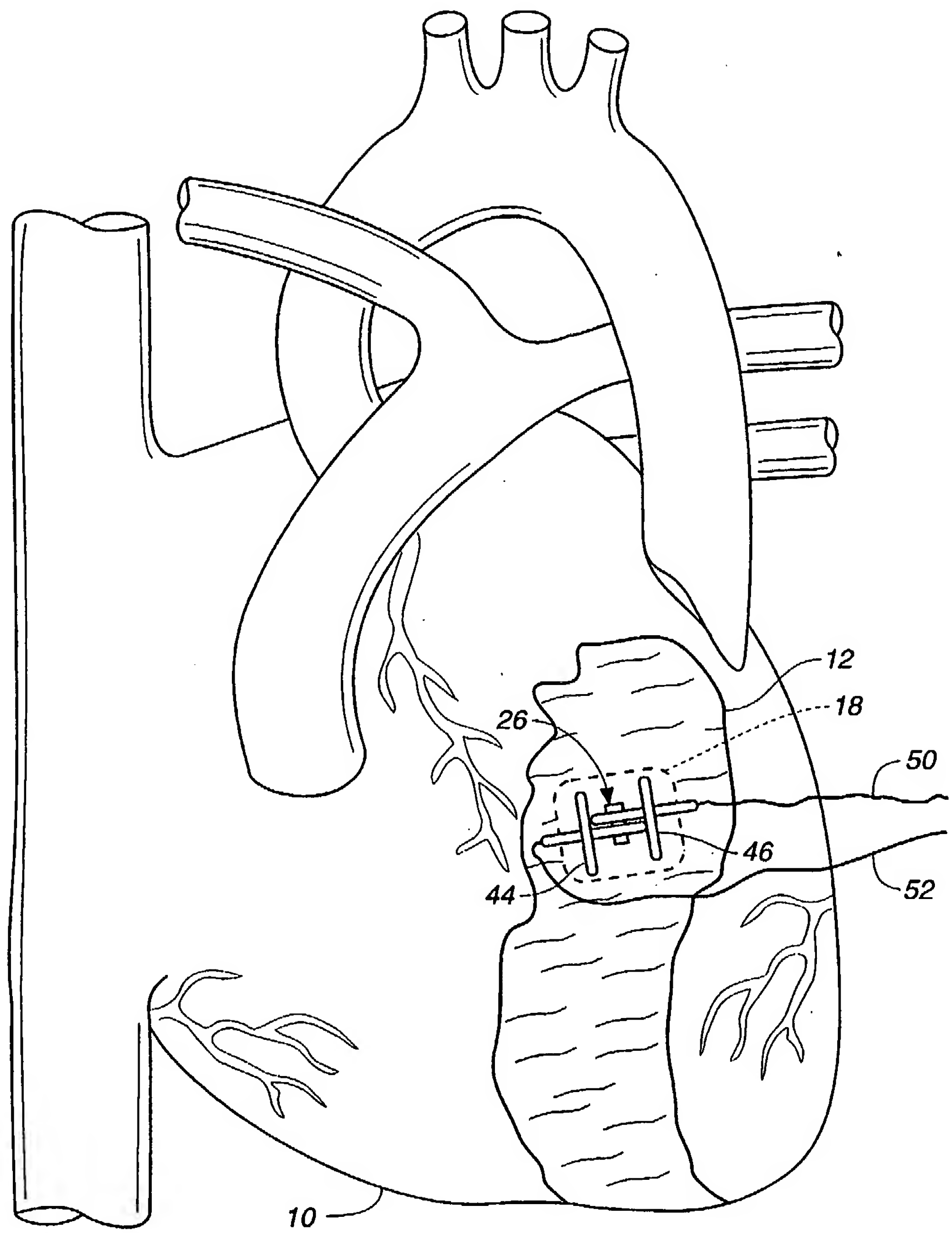

FIG._5

INTERNATIONAL SEARCH REPORT

International application No.
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A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 7/00
US CL :607/096
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/374, 439, 459; A607/96-99, 101-102, 119-111, 126-128

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

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Text Search

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,551,427 A (ALTMAN) 03 September 1996, entire document.	1-37
A	US 5,323,781 A (IDEKER et al) 28 June 1994, entire document.	1-37

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
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Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer RYAN CARTER
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(71) Applicant: ACORN MEDICAL, INC. [US/US]; Suite 421, 9900 Bren Road East, Minnetonka, MN 55343 (US).

(72) Inventor: ALFERNESS, Clifton, A.; 2022 – 235th Place N.E., Redmond, WA 98053 (US).

(74) Agent: BRUESS, Steven, C.; Merchant, Gould, Smith, Edell, Welter & Schmidt, P.A., 3100 Norwest Center, 90 South Seventh Street, Minneapolis, MN 55402-4131 (US).

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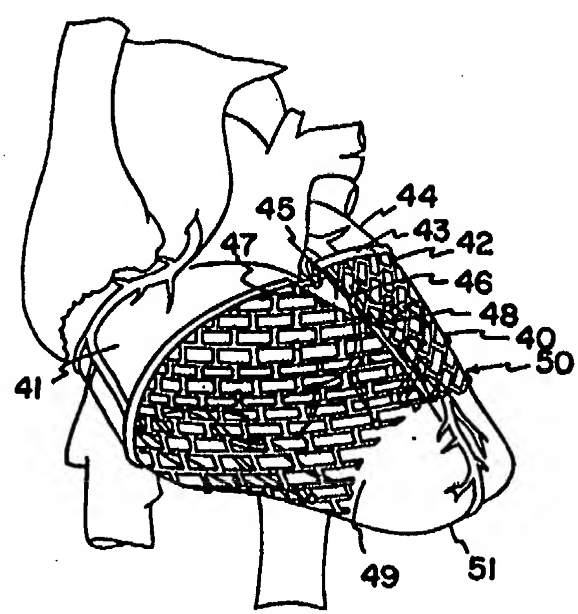
(57) Abstract

The present disclosure is directed to a cardiac reinforcement device (CRD) and method for the treatment of cardiomyopathy. The CRD provides for reinforcement of the walls of the heart by constraining cardiac expansion, beyond a predetermined limit, during diastolic expansion of the heart. A CRD of the invention can be applied to the epicardium of the heart to locally constrain expansion of the cardiac wall or to circumferentially constrain the cardiac wall during cardiac expansion.



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HEART VOLUME LIMITING DEVICE

Background of the Invention

The present invention is generally directed to a device and method for reinforcement of the cardiac wall. The invention is particularly suited for the treatment of cardiac disease which result in atrial or ventricular dilation. The invention provides reinforcement of the cardiac wall during diastolic chamber filling to prevent or reduce cardiac dilation in patients known to have experienced such dilation or who have a predisposition for such dilation occurring in the future. The cardiac reinforcement structure is typically applied to the epicardial surface of the heart.

Cardiac dilation occurs with different forms of cardiac disease, including heart failure. In some cases, such as post-myocardial infarction, the dilation may be localized to only a portion of the heart. In other cases, such as hypertrophic cardiomyopathy, there is typically increased resistance to filling of the left ventricle with concomitant dilation of the left atria. In dilated cardiomyopathy, the dilation is typically of the left ventricle with resultant failure of the heart as a pump. In advanced cases, dilated cardiomyopathy involves the majority of the heart.

With each type of cardiac dilation, there are associated problems ranging from arrhythmias which arise due to the stretch of myocardial cells, to leakage of the cardiac valves due to enlargement of the valvular annulus. Devices to prevent or reduce dilation and thereby reduce the consequences of dilation have not been described. Patches made from low porosity materials, for example Dacron™, have been used to repair cardiac ruptures and septal defects, but the use of patches to support the cardiac wall where no penetrating lesion is present has not been described.

Drugs are sometimes employed to assist in treating problems associated with cardiac dilation. For example, digoxin increases the contractility of the cardiac muscle and thereby causes enhanced emptying of the dilated cardiac chambers. On the other hand, some drugs, for example, beta-blocking drugs, decrease the contractility of the heart and thus increase the likelihood of dilation. Other drugs including angiotensin-converting enzyme inhibitors such as enalopril help to reduce the tendency of the heart to dilate under the increased diastolic pressure experienced when the contractility of the heart muscle decreases. Many of these drugs, however, have side effects which make them undesirable for long-term use.

Accordingly, there is a need for a device that can reduce or prevent cardiac dilation and reduce the problems associated with such dilation.

Summary of the Invention

The present invention is directed to a device and method for reinforcement of the cardiac wall. According to the invention, a cardiac reinforcement device includes a biomedical material which can be applied to the epicardial surface of the heart and which expands to a predetermined size that is selected to constrain cardiac expansion beyond a predetermined limit. A biomedical material suitable for a cardiac reinforcement device can be an elastic or non-elastic mesh or non-mesh material.

In one embodiment, a cardiac reinforcement device is a biomedical material in the form of a patch. The size of the patch is selected to locally constrain cardiac expansion.

In another embodiment, a cardiac reinforcement device is a biomedical material shaped as a jacket with a predetermined size selected for the jacket to surround the epicardial surface of the heart and circumferentially constrain cardiac expansion. In one embodiment, a cardiac reinforcement jacket may be applied to the epicardial surface via a minimally invasive procedure such as thorascopy.

A cardiac reinforcement jacket can include a securing arrangement for securing the jacket to the epicardial surface of the heart. The cardiac reinforcement jacket can also include a mechanism for selectively adjusting the predetermined size of the jacket around the epicardial surface of the heart. The adjustment mechanism can include a slot having opposing lateral edges which when pulled together decrease the volumetric size of the jacket. In an alternative embodiment, a selective size adjustment mechanism can include an inflatable member mounted between the jacket and the epicardial surface of the heart. Inflation of the inflatable member provides for reduction in the volumetric size of the jacket.

A cardiac reinforcement device of the invention can be used to treat cardiomyopathy or to reduce the diastolic volume of the heart.

Brief Description of the Drawings

FIG. 1 is a frontal view of one embodiment of a cardiac reinforcement patch.

FIG. 2 is a perspective view of the cardiac reinforcement patch of FIG. 1 in place on the epicardium of a heart.

FIG. 3 is a perspective view of one embodiment of a cardiac reinforcement jacket according to the invention.

FIG. 4 is a second embodiment of a cardiac reinforcement jacket according to the invention.

FIG. 5 is a perspective view of the embodiment of the cardiac reinforcement jacket shown in FIG. 3 in place around the heart.

FIG. 6 is a schematic cross sectional view of one embodiment of a mechanism for selectively adjusting the predetermined size of a cardiac reinforcement jacket.

FIG. 7 is a perspective view of a placement tool which can be used for applying a cardiac reinforcement jacket.

FIG. 8 is a perspective view of a placement tool being employed to place a cardiac reinforcement jacket over the heart.

Detailed Description

The present invention is directed to reinforcement of the heart wall during diastolic filling of a chamber of the heart. The invention is particularly suited for use in cardiomyopathies where abnormal dilation of one or more chambers of the heart is a component of the disease.

As used herein, "cardiac chamber" refers to the left or right atrium or the left or right ventricle. The term "myocardium" refers to the cardiac muscle comprising the contractile walls of the heart. The term "endocardial surface" refers to the inner walls of the heart. The term "epicardial surface" refers to the outer walls of the heart.

The heart is enclosed within a double walled sac known as the pericardium. The inner layer of the pericardial sac is the visceral pericardium or epicardium. The outer layer of the pericardial sac is the parietal pericardium.

According to the present invention, a cardiac reinforcement device (CRD) limits the outward expansion of the heart wall during diastolic chamber filling beyond a predetermined size. The expansion constraint applied to the heart by a CRD is predetermined by the physician based on, for example, cardiac output performance or cardiac volume. In contrast to known ventricular assist devices which provide cardiac assistance during systole, a CRD according to the present disclosure provides cardiac reinforcement during diastole.

A CRD is made from a biomedical material which can be applied to the epicardial surface of the heart. As used herein, a "biomedical material" is a material which is physiologically inert to avoid rejection or other negative inflammatory response. A CRD can be prepared from an elastic or substantially non-elastic biomedical material. The biomedical material can be inflexible, but is preferably sufficiently flexible to move with the expansion and contraction of the

heart without impairing systolic function. The biomedical material should, however, constrain cardiac expansion, during diastolic filling of the heart, to a predetermined size. Examples of suitable biomedical materials include perforate and non-perforate materials. Perforate materials include, for example, a mesh such as a polypropylene or polyester mesh. Non-perforate materials include, for example, silicone rubber.

A biomedical material suitable for a device of the invention generally has a lower compliance than the heart wall. Even though the biomedical material is less compliant than the heart wall, some limited expansion of an elastic biomedical material can occur during cardiac filling.

In an alternative embodiment, the biomedical material can be substantially non-elastic. According to this embodiment, the term "substantially non-elastic" refers to a material which constrains cardiac expansion during diastole at a predetermined size, but which has substantially no elastic properties.

Regardless if the biomedical material is elastic or non-elastic, advantageous to a CRD according to the present disclosure is cardiac reinforcement which is provided during diastole. Moreover, a CRD as disclosed herein does not provide cardiac assistance through active pumping of the heart.

I. CRD Patch

In one embodiment, a cardiac reinforcement device (CRD) provides for local constraint of the heart wall during cardiac expansion. According to this embodiment, a CRD is a "patch" that provides reinforcement of the heart wall at a localized area, such as a cardiac aneurysm or at an area of the myocardium which has been damaged due to myocardial infarction. When discussing a "patch", "predetermined size" of the patch means that the size of the patch is selected to cover an area of the epicardial surface of the heart in need of reinforcement without completely surrounding the circumference of the heart.

A CRD patch can be prepared from the biomedical materials described above. In a preferred embodiment, the patch is an open mesh material.

A CRD patch can be applied to the epicardial surface of the heart over or under the parietal pericardium. A patch is typically applied to the epicardial surface by suturing around the periphery of the patch. The peripheral edge of the patch can include a thickened "ring" or other reinforcement to enhance the strength of the patch at the point of suture attachment to the epicardium. Generally, a patch is applied to the epicardium through a thoracotomy or other incision providing sufficient exposure of the heart.

II. CRD Jacket

In another embodiment, a CRD is a jacket that circumferentially surrounds the epicardial surface of the heart. When applied to the heart, a CRD jacket can be placed over or under the parietal pericardium.

A CRD applied to the epicardium is fitted to a "predetermined size" for limitation of cardiac expansion. According to a jacket embodiment, "predetermined size" refers to the predetermined expansion limit of the jacket which circumferentially constrains cardiac expansion during diastolic filling of the heart. In practice, for example, a physician could measure cardiac output and adjust the jacket size to an optimal size for the desired effect. In this example, the optimal size is the "predetermined size". In one embodiment, the predetermined size can be adjusted for size reduction as the cardiac size is reduced.

In one embodiment, the CRD jacket is a cone-shaped tube, having a base broader than the apex, which generally conforms to the external geometry of the heart. When applied to the epicardial surface of the heart, the base of the jacket is oriented towards the base of the heart, and the apex of the jacket is oriented towards the apex of the heart. Typically, the base of the jacket includes an opening for applying the jacket by passing the jacket over the epicardial surface of the heart. The apical end of the jacket can be a continuous surface which covers the apex of the heart. Alternatively, the apex of the jacket can have an opening through which the apex of the heart protrudes.

A cardiac reinforcement jacket, as disclosed herein, is not an inflatable device that surrounds the heart. Rather, the device is typically a single layer of biomedical material. In one embodiment discussed below, an inflatable member can be included with the device, but the inflatable member serves to reduce the volume within a localized region of the jacket and does not follow the entire jacket to surround the epicardial surface of the heart.

In one embodiment, the CRD jacket can be secured to the epicardium by a securing arrangement mounted at the base of the jacket. A suitable securing arrangement includes, for example, a circumferential attachment device, such as a cord, suture, band, adhesive or shape memory element which passes around the circumference of the base of the jacket. The ends of the attachment device can be fastened together to secure the jacket in place. Alternatively, the base of the jacket can be reinforced for suturing the base of the jacket to the epicardium.

Various sized CRD jackets can be prepared such that different sized jackets are used for different predetermined cardiac expansion sizes or expansion ranges. Alternatively, a CRD jacket can include a mechanism for selectively adjusting the size of the jacket. A mechanism for selectively adjusting the

volumetric size of the jacket theoretically provides for a "one size fits all" device. More importantly, however, an adjustable jacket provides the ability to titrate (readjust) the amount of cardiac reinforcement by graded reduction in jacket size as therapeutic reduction of cardiac expansion occurs.

A mechanism for selectively adjusting the size of the jacket can include a slot which opens at the base of the jacket and extends toward the apex end of the CRD. If the apex end of the CRD jacket is open, the apical extent of the slot can be continuous with the apex opening. The slot includes opposing lateral edges. By adjusting the proximity of the opposing lateral edges, the overall size of the jacket can be varied. Moving the opposing edges of the slot closer together narrows the slot and reduces the volumetric size of the jacket. The opposing edges of the slot can be fastened together at a predetermined proximity by, for example, one or more lateral attachment devices, such as a cord, suture, band, adhesive or shape memory element attached to each lateral edge.

In another embodiment, a mechanism for selectively adjusting the size of the jacket can be an inflatable member. According to this embodiment, the inflatable member is mounted between the jacket and the epicardium. The volumetric size of the jacket can be reduced by inflating the inflatable member through an inflation port with, for example, a gas or liquid. As cardiac expansion volume responds to cardiac constraint by size reduction, the predetermined size of the jacket can then be reduced by inflating the inflatable member within the jacket. Once inflated, the size of the inflatable member is preferably maintained until therapeutic response causes a need for further inflation. According to the invention, the inflation of the inflatable member provides a reduction in the predetermined size of the jacket by a fixed increase in volume of the inflatable member. The inflatable member is not rhythmically inflated and deflated to provide assistance to cardiac contraction during systole.

The biomedical material of the invention can be radioluscent or radiopaque. In one embodiment, the material of the jacket can be made radiopaque by inclusion of radiopaque markers for identification of the outside surface of the heart, the expansion slot or inflation port. As used herein, radiopaque means causing the CRD to be visible on x-ray or fluoroscopic viewing. Suitable radiopaque markers include, for example, platinum wires, titanium wires and stainless steel wires.

A CRD according to the present disclosure provides a new method for the treatment of cardiac disease. As used herein, cardiac disease includes diseases in which dilation of one of the chambers of the heart is a component of the disease. Examples include heart failure or cardiomyopathy. Heart failure can occur

as a result of cardiac dilation due to ventricular hypertrophy or secondary to, for example, valvular incompetency, valvular insufficiency or valvular stenosis. Cardiomyopathy, according to the invention, can be primary or secondary to infection, ischemia, metabolic disease, genetic disorders, etc.

It is foreseen that constraint of cardiac expansion by a device of the invention can provide reduced cardiac dilation. Reduced cardiac dilation can cause reduction in the problems associated with cardiac dilation such as arrhythmias and valvular leakage. As reduction of cardiac dilation occurs, selective reduction of the predetermined size of the jacket also provides continued reinforcement for the size reduced heart.

A CRD jacket can also be used to measure cardiac performance. According to this embodiment, the CRD jacket is rendered radiopaque by use of a radiographic marker. The radiographic markers are distributed throughout the jacket over the surface of the heart. By evaluation of the markers relative to one another with each heart beat, cardiac performance may be measured. As such, evaluation of cardiac performance may assist in adjusting the predetermined size of a CRD jacket.

A CRD as described herein can be applied to the epicardium of a heart through a thoracotomy or through a minimally invasive procedure. For a minimally invasive procedure a CRD placement tool can be used to apply the CRD over the epicardium of the heart through a thorascopic incision. According to this embodiment, a CRD placement tool includes a cannula, a stiff rod or wire and a guide tube. For placement of a CRD, the wire is threaded through the guide tube which is passed around the circumference of the base of the jacket. The CRD with wire and guide tube passed through the base opening are then passed into the cannula. The cannula is of sufficient length and diameter to enclose the CRD, wire and guide tube during passage of the placement tool through a thorascopic incision. The placement tool is passed into the thoracic cavity and positioned at a point near the apex of the heart. When in position, the wire and guide tube are pushed out of the cannula away from the operator. Once outside the cannula, the wire and guide tube sufficiently expand the opening of the base of the CRD jacket to pass over the epicardial surface of the heart. When the CRD jacket is in position over the epicardial surface, the wire, guide tube and cannula can be removed. A second incision can then be made to provide access for suitable surgical instruments to secure or adjust the size of the CRD.

The invention will now be further described by reference to the drawings.

FIG. 1 is a frontal view of one embodiment of a cardiac reinforcement patch 1. The CRD patch 1 shown here is a mesh biomedical material

2 having a thickened peripheral ring **3** which reinforces the peripheral edge **4** of the patch for attachment of the patch to the epicardial surface of the heart.

FIG. 2. is a perspective view of a CRD patch **10** in place on the epicardial surface of a heart **11**, for example, over a cardiac aneurysm (not shown) of the heart. In one preferred embodiment, the patch **10** is sized to cover the extent of the cardiac aneurysm and is placed on the epicardial surface of the heart **11**. In practice, the thorax is surgically opened and the region of the heart **11** with the aneurysm (not shown) is located and exposed. The patch **10** is placed over the aneurysm and sutured in place around the periphery **12** of the patch to provide sufficient constraint to prevent further dilation of the aneurysm.

FIG. 3 is a perspective view of one embodiment of a CRD jacket **15** according to the invention. According to the embodiment shown, the jacket **15** is a mesh material **16**, and includes a circumferential attachment device **17** at the base end **18** of the CRD jacket. The apex end **24** of the jacket **15** is closed. The jacket **15** shown also includes a slot **19** having opposing lateral edges **20** and **21**, and fasteners (e.g. lateral attachment device **22** and **23**) for selectively adjusting the volumetric size of the jacket **15**. The CRD jacket **15** shown also includes radiopaque markers **25** for visualizing the surface of the heart through radiographic study.

FIG. 4 is an alternative embodiment of a CRD jacket **30**. Similar to the embodiment shown in FIG. 3, the embodiment of FIG. 4 includes a base end **31** and an apex **32** end. The base end includes a circumferential attachment device **33** for securing the CRD jacket **30** to the heart. The CRD jacket **30** of FIG. 4 also includes a slot **34** having opposing lateral edges **35, 36**. The lateral edges **35, 36** are shown pulled together at **37** by a lateral attachment device **38**, for example, a suture. In contrast to the embodiment shown in FIG. 3, the embodiment shown in FIG. 4 has an opening **39** at the apex end **32** of the CRD jacket **30**.

FIG. 5. is a perspective view of a CRD jacket **40** around a heart **41**. According to the embodiment shown, at the base **42** of the jacket **40**, there is a circumferential attachment device **43** which secures the CRD jacket **40** near the base of the heart **44**. A slot **45**, is shown with opposing lateral edges **46, 47** fastened together by a lateral attachment device **48**. In the embodiment shown, the CRD jacket **40** has an opening **49** at the apical end **50** of the jacket. The apex of the heart **51** protrudes through the opening **49** at the apical end **50** of the jacket **40**.

Still referring to FIG. 5, in a preferred embodiment, if one or more of the lateral attachment device **48** are made of an elastic material, such as silicone rubber, the device can provide a way of applying a graded constraint around the outside of the heart **41** to reduce cardiac dilation over time. In practice, the jacket would be placed over the heart **41** as shown, either over or under the parietal

pericardium (not shown). The circumferential attachment device **43** and lateral attachment device **48** would then be tightened to cause a constraining effect on the outside of the heart.

In a preferred embodiment, if one or more of the lateral attachment cords **48** is made of an elastic material, such as silicone rubber, surface pressure exerted on the epicardial surface of the heart varies as a function of the amount of dilation of the heart. This variable pressure has the effect of reducing the cardiac dilation to a certain point and then stopping because the surface pressure drops to a negligible amount. The amount of constraint or reduction in dilation that is accomplished over time and the resultant cardiac performance may be monitored radiographically using techniques known in the art, for example fluoroscopy, by observing radiographic markers (FIG. 4, **25**), if present.

FIG. **6** is a schematic cross sectional view of an alternative embodiment of an arrangement for selectively adjusting the predetermined size of a jacket **53**. According to this embodiment, an inflatable member **54** is inserted within the jacket **53** between the jacket **53** and the epicardial surface **55** of the heart **56**. The inflatable member **54** includes a filling apparatus **57** for entry of a fluid (liquid or gas) to inflate the inflatable member **54** and reduce the predetermined size of the jacket **53**.

FIG. 7 is a perspective view of a placement tool **60** which can be used for placement of a CRD jacket **61** around the epicardium of the heart. As shown here, the base end of the jacket **62** is held open by guide tube **63** through which is passed a wire or stiffening rod **64**. The wire **64** can be removed from the guide tube **63** by pulling on the wire extraction grip **66**. The placement tool **60** includes a cannula **65** which encloses the jacket **61**, guide tube **63** and wire **64** during insertion of the tool into a thorascopic incision.

FIG. **8** is a perspective view of a placement tool **70** being employed to place a jacket **71** over the heart **72** on the outside of the parietal pericardium **73**. The placement tool **70** is guided through a small incision in the thorax and the jacket **71** is maneuvered into position over the heart **72**. Once the jacket **71** is in proper position, the wire **74**, which is passed through the guide tube **75** around the base **76** of the jacket **71**, is extracted from the guide tube **75** by pulling on the wire extraction grip **77**. The guide tube **75** is then extracted by pulling on the guide tube extraction grip **78**. The cannula **79** is removed from the chest and the circumferential attachment cord (not shown in this view), and the lateral attachment cord **80** can be fastened to secure the jacket **71**.

The above specification and drawings provide a description of a cardiac reinforcement device and method of using on the heart. Since many

embodiments of the invention can be made without departing from the spirit and scope of the invention, the invention resides in the claims hereinafter appended.

<u>WHAT IS CLAIMED IS</u>:

1. A cardiac reinforcement device, said device comprising:
   - a biomedical material which can be applied to the epicardial surface of the heart and which expands to a predetermined size,

   said predetermined size selected to constrain cardiac expansion beyond a predetermined limit.

2. The cardiac reinforcement device according to claim 1 wherein said biomedical material is an open mesh patch, said size selected for said patch to locally constrain cardiac expansion.

3. The cardiac reinforcement device according to claim 1 wherein said biomedical material is a jacket with said predetermined size selected for said jacket to surround the epicardial surface of the heart and circumferentially constrain cardiac expansion.

4. The cardiac reinforcement device according to claim 3 wherein said jacket has a base end, said base end having an opening for applying said jacket to the epicardial surface of the heart by passing the jacket over the epicardial surface of the heart such that when applied to said epicardial surface, said base end of said jacket is oriented toward the base of the heart.

5. The cardiac reinforcement device according to claim 3 wherein said jacket has an apex end such that when said jacket is applied to said epicardial surface, said apex end is oriented towards the apex of the heart.

6. The cardiac reinforcement device according to claim 5 wherein said apex end of said jacket has an opening for protrusion of the apex of the heart therethrough.

7. The cardiac reinforcement device according to claim 4 wherein said base end of said jacket further includes a securing arrangement for securing said jacket to said epicardial surface of the heart.

8. The cardiac reinforcement device of claim 7 wherein said securing arrangement for securing said jacket to said epicardial surface of the heart is

a circumferential attachment device which surrounds said opening at said base end of said jacket.

9. The cardiac reinforcement device according to claim 4 wherein said jacket includes a mechanism for selectively adjusting said predetermined size of said jacket surrounding the epicardial surface of the heart.

10. The cardiac reinforcement device according to claim 9 wherein said mechanism for selectively adjusting said predetermined size of said jacket is a slot, said slot having opposing lateral edges which decrease said predetermined size by moving said opposing lateral edges closer together.

11. The cardiac reinforcement device according to claim 10 including a lateral attachment device for fastening together said lateral opposing edges of said slot.

12. The cardiac reinforcement device according to claim 9 wherein said mechanism for selectively adjusting said predetermined size of said jacket is an inflatable member mounted between said jacket and the epicardial surface.

13. The cardiac reinforcement device according to claim 1 wherein said biomedical material is an open mesh material.

14. The cardiac reinforcement device according to claim 1 wherein said biomedical material is a polyester mesh.

15. The cardiac reinforcement device according to claim 1 wherein said biomedical material is silicon rubber.

16. The cardiac reinforcement device according to claim 1 wherein said biomedical material includes a radiopaque marker.

17. The cardiac reinforcement device according to claim 16 wherein said radiopaque marker is a platinum wire.

18. A cardiac reinforcement device, said device comprising:

- a jacket of a biomedical material which can be applied to the epicardial surface of the heart and which expands to a predetermined

size, said predetermined size selected to surround the epicardial surface of the heart and circumferentially constrain cardiac expansion beyond a predetermined limit, said jacket comprising:

(i) a base end, said base end having an opening for applying said jacket to the epicardial surface of the heart by passing said jacket over the epicardial surface of the heart such that when applied to said epicardial surface, said base end of said jacket is oriented toward the base of the heart; and

(ii) a slot for selectively adjusting said predetermined size of said jacket, said slot having opposing lateral edges which decrease said predetermined size of said jacket by moving said opposing lateral edges together.

19. A cardiac reinforcement device, said device comprising:

- a jacket of a biomedical material which can be applied to the epicardial surface of the heart and which expands to a predetermined size, said predetermined size selected to surround the epicardial surface of the heart and circumferentially constrain cardiac expansion beyond a predetermined limit, said jacket comprising:

(i) a base end, said base end having an opening for applying said jacket to the epicardial surface of the heart by passing said jacket over the epicardial surface of the heart such that when applied to said epicardial surface, said base end of said jacket is oriented toward the base of the heart; and

(ii) an inflatable member mounted between said jacket and the epicardial surface of the heart for selectively adjusting said predetermined size of said jacket.

20. The cardiac reinforcement device according to claim 19 wherein said biomedical material is an open mesh material.

21. The cardiac reinforcement device according to claim 19 wherein said biomedical material is a polyester mesh.

22. A cardiac reinforcement device, said device comprising:

(a) a cone-shaped biomedical material having an apical end and a based end and which generally conforms to the external geometry of a patient's heart;

(b) said cone-shaped biomedical material having a lateral slot providing for selective adjustment of a circumference of said cone-shaped biomedical material to a predetermined size;

(c) said predetermined size selected to surround the surface of the heart and constrain cardiac expansion beyond a predetermined limit.

23. The cardiac reinforcement device according to claim 22 wherein said cone-shaped biomedical material is substantially non-elastic.

24. The cardiac reinforcement device according to claim 22 wherein said slot has opposing lateral edges which decreases said predetermined size of said circumference of said cone-shaped device by moving said opposing lateral edges together.

25. The cardiac reinforcement device according to claim 22 wherein said apical end of said device is open.

26. The cardiac reinforcement device according to claim 22 wherein said biomedical material is an open mesh material.

27. A cardiac reinforcement device for constraining cardiac size during diastole, said device comprising:

(a) a biomedical material for contacting an epicardial surface of a patient's heart and configured to circumferentially surround said epicardial surface of said patient's heart;

(b) said configured biomedical material having a base end and an apical end; and

(c) said configured biomedical material providing cardiac constraint during diastole without substantially assisting cardiac contraction during systole.

28. The cardiac reinforcement device according to claim 27 wherein said biomedical material is substantially non-elastic.

29. The cardiac reinforcement device according to claim 27 wherein said configured biomedical material has a lateral slot for providing selective adjustment of a circumference of said biomedical material to a predetermined size.

30. The cardiac reinforcement device according to claim 29 wherein said slot has opposing lateral edges which decrease said predetermined size of said circumference of said biomedical material by moving said opposing lateral edges together.

31. The cardiac reinforcement device according to claim 27 wherein said apical end of said device is open.

32. A method for treating cardiac disease, said method comprising:
   (a) selecting a cardiac reinforcement device, said cardiac reinforcement device comprising:
      (i) a biomedical material which can be applied to the epicardial surface of the heart and which expands to a predetermined size, said predetermined size selected to constrain cardiac expansion beyond a predetermined limit;
   (b) applying said cardiac reinforcement device to the epicardial surface of the heart; and
   (c) securing said cardiac reinforcement device to said epicardial surface of the heart.

33. The method according to claim 32 wherein said cardiac reinforcement device is a jacket with said predetermined size selected for said jacket to surround the epicardial surface of the heart and circumferentially constrain cardiac expansion.

34. The method according to claim 32 wherein said cardiac reinforcement device is a patch, said size selected for said patch to locally constrain said cardiac expansion.

35. The method according to claim 32 wherein said cardiac reinforcement device is applied to the epicardial surface of the heart under the parietal layer of the pericardium.

36. The method according to claim 33 wherein said cardiac reinforcement device is applied to said epicardial surface via thorascopy.

37. The method according to claim 32 wherein said cardiac disease is heart failure.

38. The method according to claim 32 wherein said cardiac disease is cardiomyopathy.

39. The method according to claim 33 wherein said predetermined size of said jacket is reduced as cardiac size is reduced.

40. A method for reducing the diastolic volume of the heart, said method comprising:

(a) selecting a cardiac reinforcement device, said cardiac reinforcement device comprising:

(i) a biomedical material which can be applied to the epicardial surface of the heart and which expands to a predetermined size, said predetermined size selected to constrain cardiac expansion beyond a predetermined limit;

(b) applying said cardiac reinforcement device to the epicardial surface of the heart; and

(c) securing said cardiac reinforcement device to said epicardial surface of the heart.

41. A method for treating valvular conditions of a patient's heart, said method comprising:

(a) selecting a cardiac reinforcement device, said cardiac reinforcement device comprising:

(i) a biomedical material which can be applied to an epicardial surface of the heart and having a maximum predetermined size, said predetermined size selected to constrain cardiac expansion beyond a predetermined limit;

(b) applying said cardiac reinforcement device to said surface of the heart; and

(c) securing said cardiac reinforcement device to said surface of the heart.

42. The method for treating valvular conditions according to claim 41 wherein said valvular condition is valvular insufficiency.

43. The method for treating valvular conditions according to claim 41 wherein said biomedical material is a substantially non-elastic material.

44. A method for minimally invasive treatment of cardiac disease of a patient's heart, said method comprising:
   (a) passing a thorascope into a first incision in said patient for intra thoracic visualization;
   (b) inserting a cardiac reinforcement device into a second incision in said patient's thorax, said cardiac reinforcement device comprising:
      (i) a biomedical material which can be applied to an epicardial surface of the heart and having a maximum predetermined size, said predetermined size selected to surround the surface of the heart and circumferentially constrain cardiac expansion beyond a predetermined limit;
   (c) applying said cardiac reinforcement device to said epicardial surface of said patient's heart;
   (d) removing said thorascope from said patient's thorax;
   (e) closing said first and said second incision in said patient's thorax.

45. The method according to claim 44 wherein said cardiac reinforcement device comprises:
   (a) a jacket having a base end and an apical end, said base end having an opening for applying said jacket to the surface of the heart by passing said jacket over said surface of the heart such that when applied to the surface, the base of the jacket is oriented toward the base of the heart.

46. The method according to claim 45 wherein said cardiac reinforcement device further comprises:
   (a) a cannula for passing said cardiac reinforcement device through said second incision;
   (b) a guide tube, said guide tube capable of passing around a circumference of said base of said jacket;
   (c) a guide wire capable of passing through said guide tube.

47. The method according to claim 46 further comprising a step of:
   (a) passing said cannula into said second incision to a position for applying said jacket to said patient's heart;
   (b) passing through said cannula into said patient's thorax said jacket having said guide tube passed around said circumference of said base of said jacket and said guide wire passed through said guide tube;

(c) applying said jacket over said surface of said heart such that said base of said jacket is oriented towards the base of said heart;

(d) removing said guide wire from said guide tube;

(e) removing said guide tube from said base of said jacket; and

(f) removing said cannula from said patient.

FIG. 1

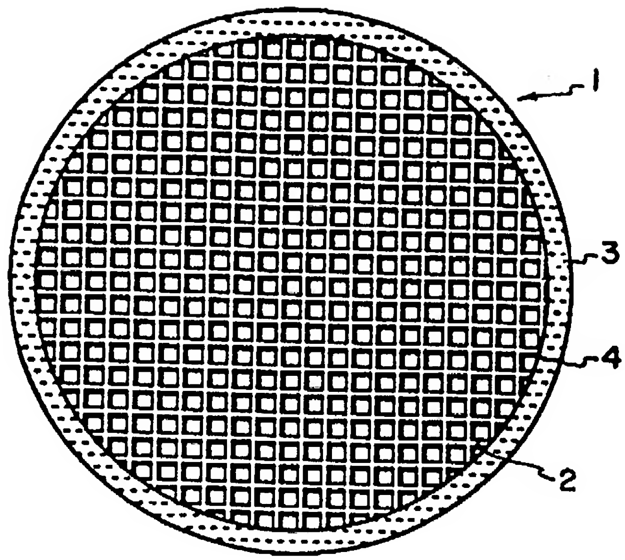


FIG. 2

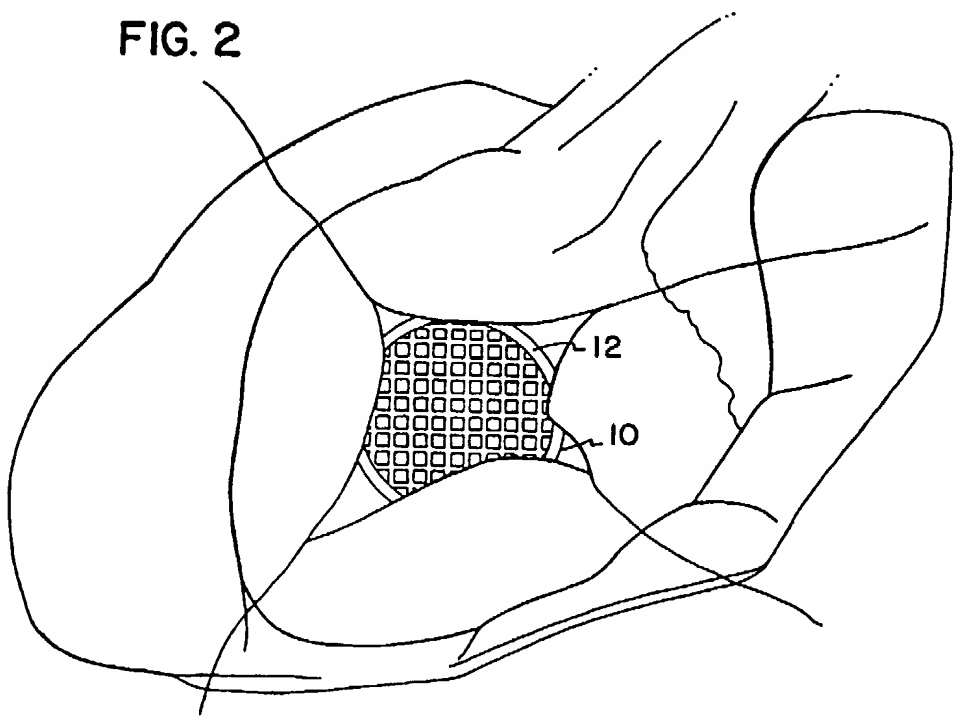


FIG. 3

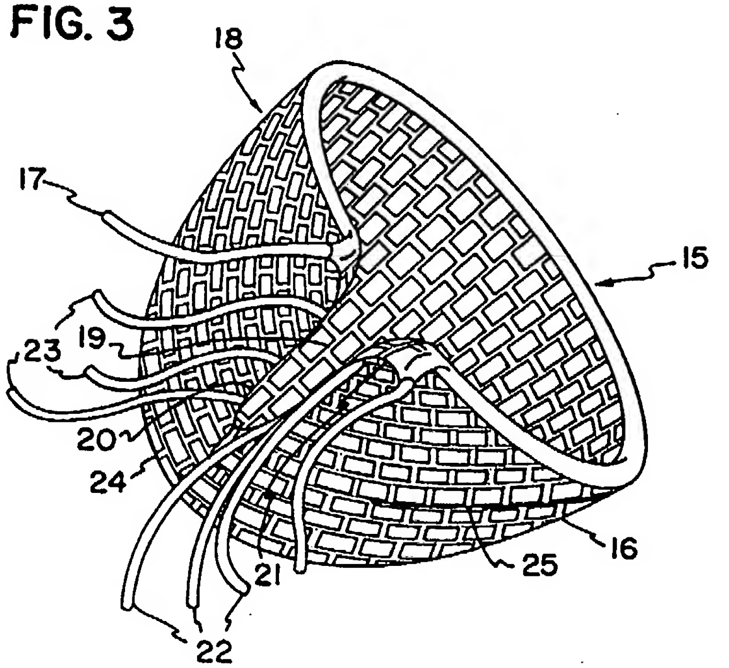


FIG. 4

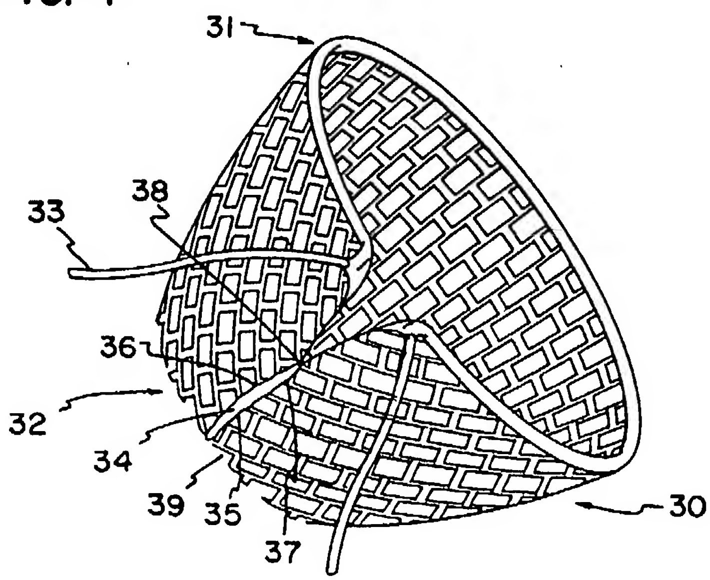


FIG. 5

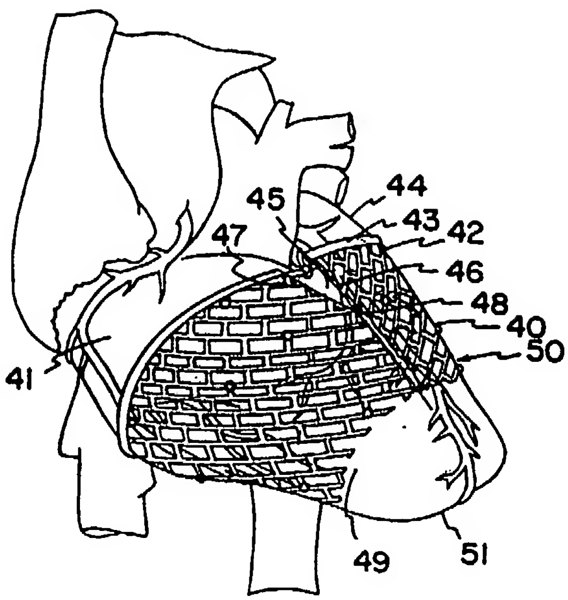


FIG. 6

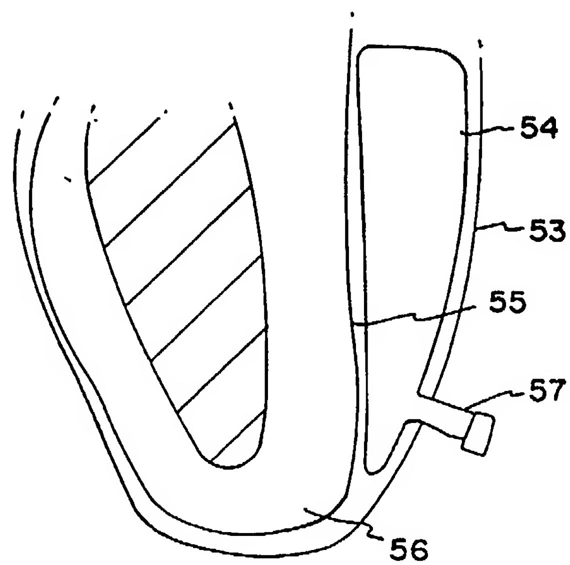


FIG. 7

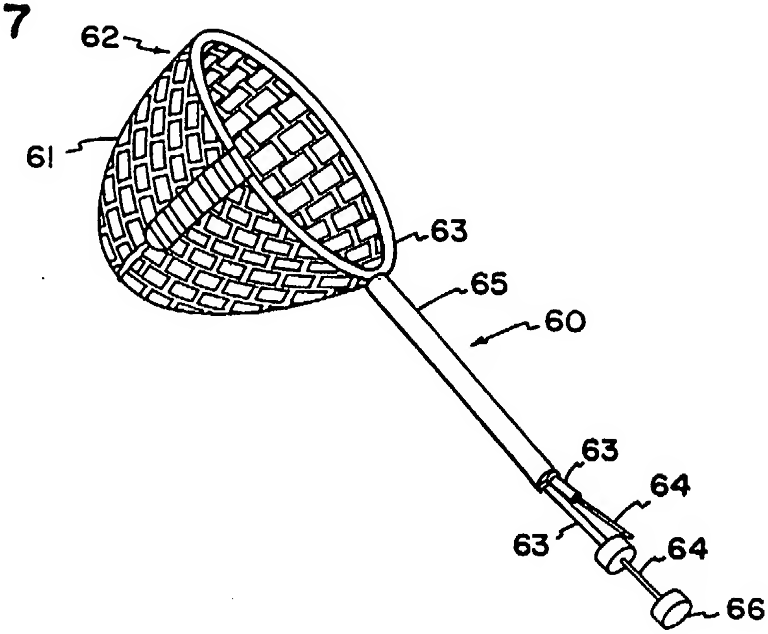
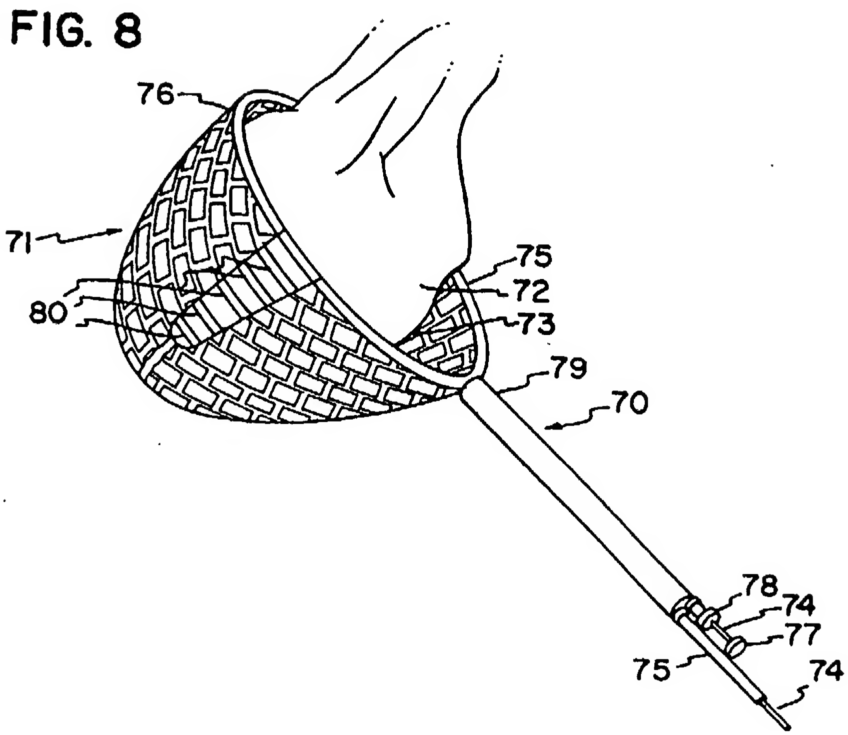


FIG. 8



INTERNATIONAL SEARCH REPORT

Intern: al Application No
PCT/US 97/17898

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,A	US 5 603 337 A (JARVIK) 18 February 1997 see abstract; figure 2 ---	1,18,19, 22,27
A	US 4 403 604 A (WILKINSON) 13 September 1983 see abstract; figures 1,2 ---	1,18,19, 22,27
A	US 5 507 779 A (ALTMAN) 16 April 1996 see abstract; figure 4 -----	1,18,19, 22,27

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

1

Date of the actual completion of the international search	Date of mailing of the international search report
17 February 1998	23.02.98

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Papone, F

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 97/17898

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 32-47
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 97/17898

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5603337 A	18-02-97	NONE	
US 4403604 A	13-09-83	NONE	
US 5507779 A	16-04-96	NONE	